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K020256

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ....3M ESPE AG

Street:..ESPE Platz

ZIP-Code, City:..................................D-82229 Seefeld

Federal State:....................................Bavaria

Country:...Germany

Establishment Registration Number 9611385

Contact:...Dr. Andreas Petermann, Manager U.S. Regulatory Affairs

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Date:..January 21, 2002

Name of Device

Proprietary Name: ....Unicem

Classification Name:............................Dental cement other than zinc oxide-eugenol

Common Name: ....Self adhesive cement

Predicate Devices

Compolute™ by 3M ESPE ....K 974458

Ketac™ Cem by 3M ESPE..................K 897188

HAUR™ by 3M ESPE ....K 010781

Protemp™ H by 3M ESPE...................K 002364

Alkaliner™ by 3M ESPE.......................K 873882

Description for the Premarket Notification

Unicem is classified as a Dental cement other than zinc oxide-eugenol (21 C.F.R. § 872.3275[b]) because it is a device composed of various materials other

than zinc oxide-eugenol. Unicem is intended to affix dental devices such as crowns and bridges.

Unicem self adhesive luting cement due to its newly developed chemistry combines the advantages of glass ionomer luting cements with esthetic properties of composite luting cements.

Unicem contains some particular ingredients which are not contained in known predicate devices. To evaluate the biocompatibility of Unicem, toxicology testing has been carried out. To provide evidence for the effectiveness, Unicem was compared to predicate devices in terms of physical and mechanical properties.

In summary, 3M ESPE's new self adhesive luting cement Unicem described in this premarket notification submission is, in our opinion, substantially equivalent to the predicate devices.

The substantial equivalence to the well established products Ketac Cem and Compolute, the performance data and the results of biocompatibility testing provide evidence that safety and effectiveness requirements of Unicem are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Andreas Petermann
Manager, U.S. Regulatory Affairs
3M ESPE AG
ESPE Platz
D-82229 Seefeld
Bavaria,
GERMANY

Re: K020256
Trade/Device Name: Unicem™
Regulation Number: 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: January 21, 2002
Received: January 24, 2002

Dear Dr. Petermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

(As Required by 21 C.F.R. § 801.109)

510(k) Number: K020256

Device Name: Unicem™

Indications for use: Adhesive fixing of ceramic, composite or metal inlays, onlays, crowns, bridges, posts, screws, veneers and orthodontic strips

Prescription use: ☑ Over-the counter use ☐

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020256